UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

TONYA WALLACE PLAINTIFF,	
V.	CIVIL ACTION NO.
BOSTON SCIENTIFIC CORPORATION (d/b/a MANSFIELD SCIENTIFIC, INC. (MICROVASIVE, INC.).	JURY TRIAL DEMANDED
	ASSESSMENT OF DAMAGES HEARING IS REQUIRED
DEFENDANT.	

CIVIL ACTION COMPLAINT
NEGLIGENCE AND PRODUCTS LIABILITY

Plaintiff, Tonya Wallace, by and through her attorneys, Lee B. Balefsky, Esquire and Christopher A. Gomez, Esquire, of Kline & Specter, P.C., files this Complaint against the Defendants. Accordingly, Plaintiff alleges as follows:

PARTIES

1. Plaintiff, Tonya Wallace ("Plaintiff) is, and was, al relevant times, a resident of Palmerton, Pennsylvania.

2. Defendant BOSTON SCIENTIFIC CORPORATION ("BOSTON SCIENTIFIC".") (d/b/a Mansfield Scientific, Inc. & Microvasive, Inc.). is a Delaware corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1 Boston Scientific Place, Natick, Massachusetts, 01760-1537.

JURISDICTION AND VENUE

3. At all relevant times, Defendant BOSTON SCIENTIFIC, the manufacturer of defective synthetic mesh systems used for both pelvic organ prolapse (POP) and stress urinary

incontinence (SUI), and said manufacturer's complete line of urogynecological medical devices, purchased and assumed all liability relating to legal claims arising from the implantation of the synthetic mesh systems.

4. Plaintiff was implanted with a product designed, manufactured and sold in interstate commerce (including Pennsylvania and California) the BOSTON SCIENTIFIC synthetic mesh systems ("subject synthetic mesh systems").

5. This Court has diversity subject-matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a), because it is a civil action in which the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs, and is between citizens of different States.

FACTUAL BACKGROUND

6. BOSTON SCIENTIFIC developed technology to diagnose and treat conditions related to the pelvic health of women. BOSTON SCIENTIFIC developed, manufactured, marketed, advertised, promoted and sold synthetic mesh systems worldwide including the systems implanted in Plaintiff.

7. Plaintiff suffered from stress urinary incontinence that required surgical intervention for repair. Plaintiff was implanted with the BOSTON SCIENTIFIC Advantage Fit Sling synthetic mesh system on July 28, 2015. The synthetic mesh systems were designed, developed, manufactured, marketed, promoted, advertised, warranted and distributed by BOSTON SCIENTIFIC.

8.. After the initial implant procedure, Plaintiff experienced complications including

but not limited to urinary issues, pelvic pain, mesh erosion and other injuries similar to the ones described in the FDA's Public Health Advisory of October 20, 2008. from the defective mesh requiring additional medical care and treatment and ultimately surgical intervention.

9. Plaintiff did not know and/or could not reasonably discover that her problems and complications were related to a defect in design or manufacture of the medical device until approximately December 9, 2016.

10. Between 2002 and the present, numerous reports of adverse events pertaining to the subject synthetic mesh system filed by physicians and patients. The most frequent complaints were erosion, extrusion, infection, hardening of the mesh, chronic pain and worsening symptoms. Published studies have shown a high rate of mesh erosion accompanied by worsening symptoms.

11. The 2004 World Health Organization 3rd International Consultation on Incontinence reported mesh repairs have unacceptable high rate of complication that include erosion, extrusion, infection, sepsis, and urination. Because of the poor risk/benefit ratio of the vaginal mesh systems it was recommended the synthetic mesh systems not to be used until more approved clinical trials of outcome were conducted.

12. On July 13, 2011, the FDA issued a Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of "continuing

serious concern." The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were not rare. These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. Moreover, the FDA concluded that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh was more effective than traditional non mesh repair of Pelvic Organ Prolapse. The FDA conducted a systematic review of the published scientific literature from 1996-2011 and concluded that based thereon, that transvaginal Pelvic Organ Prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair."

13. Additionally, in the July 13, 2011 Safety Communication, the FDA concluded that:

> "...a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible."

14. The information contained in the FDA's Safety Communication of July 13, 2011 is equally applicable to the subject synthetic mesh system and the information was known or knowable to BOSTON SCIENTIFIC and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use or labeling.

15. At all times relevant herein, the subject synthetic mesh system was widely

advertised and promoted by BOSTON SCIENTIFIC as a safe and effective treatment for pelvic organ prolapse and/or urinary incontinence repair. BOSTON SCIENTIFIC minimized the risks posed to patients with implantation of the system.

16. At all times relevant herein, BOSTON SCIENTIFIC knew there was a defect and knew the defect in the subject synthetic mesh system was attributable to the erosion, shrinkage and/or hardening of the mesh material. BOSTON SCIENTIFIC knew that the mesh is made to allow tissue infiltration and removal is not advised. Complications from the mesh and from mesh removal are life-changing and can be irreversible. This information was known to BOSTON SCIENTIFIC prior to implantation of the subject synthetic mesh system in Plaintiff.

17. At all times relevant to this action, BOSTON SCIENTIFIC knew that the synthetic mesh systems were not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise, malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries from erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions and worsening symptoms. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can take up to three surgical interventions in the operating theater for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

18. BOSTON SCIENTIFIC'S representations regarding the performance of the subject synthetic mesh systems, including, but not limited to, the consistency of the performance of the subject synthetic mesh system and their safety and reliability, were untrue as set forth in the published literature and adverse event reports. BOSTON SCIENTIFIC failed to disclose to physicians, patients or Plaintiff that its mesh was subject to material changes in

the polypropylene and/or cause erosion or excessive scar tissue and/or fibrotic formation causing the injuries herein described.

19. At all relevant times herein, BOSTON SCIENTIFIC continued to promote the subject synthetic mesh system as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

20. In doing so BOSTON SCIENTIFIC concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the subject synthetic mesh system.

21. As of the filing of this complaint, Plaintiff is more likely than not to have continuing procedures relating to injuries suffered from the defective device.

22. At all relevant times herein, BOSTON SCIENTIFIC failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the subject synthetic mesh system including, but not limited to, mesh erosion, dense adhesions, worsening symptoms, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

23. The subject synthetic mesh system as designed, manufactured, distributed sold and/or supplied by BOSTON SCIENTIFIC was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of BOSTON SCIENTIFIC's knowledge of lack of pelvic health safety.

24. At all times herein mentioned, the officers and/or directors of BOSTON SCIENTIFIC participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew the hazards and dangerous propensities of said products, and thereby actively participated in the tortuous conduct that resulted in the injuries

suffered by Plaintiff.

COUNT I
STRICT LIABILITY-DEFECTIVE MANUFACTURING AND DESIGN

25. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

26. The Defendant's Pelvic Mesh Products, were in certain instances, defectively and improperly manufactured, rendering the products deficient, and unreasonably dangerous and hazardous to Plaintiff.

27. The Defendant's Pelvic Mesh Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

28. The Pelvic Mesh Products create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far, outweigh the utility of the Pelvic Mesh Products.

29. Defendant has intentionally and recklessly designed, manufactured, marketed, labeled, sold, and distributed the Pelvic Mesh Products with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placing their economic interests above the health and safety of the Plaintiff.

30. As a proximate result of the Defendant's design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff was injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment,

loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II
STRICT LIABILITY-FAILURE TO WARN

31. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

32. The Defendant failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendant's Pelvic Mesh Products.

33. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the risks and benefits of the Defendant's Pelvic Mesh Products, given the Plaintiff's conditions and need for information.

34. The Defendant failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

35. The Defendant intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

36. As a proximate result of the Defendant's design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages

WHEREFORE, Plaintiff demands judgment against Defendant, for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT III
NEGLIGENCE

37. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

38. Defendant has a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Products, and recruitment and training of physicians to implant the Products.

39. Defendant breached its duty of care to Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the Pelvic Mesh Products.

40. As a proximate result of the Defendant's design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff has been injured catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant, for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other

relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IV
COMMONLAW FRAUD

41. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

42. Defendant falsely and fraudulently represented and continues to represent to the medical and healthcare community, Plaintiff, the FDA, and the public that the Products had been tested and were found to be safe and effective.

43. The representations made by Defendant were, in fact, false. When Defendant made its representations, Defendant knew and/or had reason to know that those representations were false, and Defendant willfully, wantonly, and recklessly disregarded the inaccuracies in its representations and the dangers and health risks to users of the Products.

44. These representations were made by Defendant with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Products for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of the Plaintiff.

45. In representations to Plaintiff and/or to Plaintiff's healthcare providers, Defendant fraudulently concealed and intentionally omitted the following material information:

a) That the Defendant's Pelvic Mesh Products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b) That the lisle of adverse events with the Defendant's Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

c) The Defendant's Pelvic Mesh Products were not adequately tested;

d) That the limited clinical testing revealed the Defendant's Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e) That Defendant deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

f) That Defendant was aware of dangers in the Defendant's Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

g) That the Defendant's Pelvic Mesh Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

h) That patients needed to be monitored more regularly than usual while using the Defendant's Pelvic Mesh Products and that in the event the products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;

i) That the Defendant's Pelvic Mesh Products were manufactured negligently;

j) That the Defendant's Pelvic Mesh Products were manufactured defectively; and

k) That the Defendant's Pelvic Mesh Products were designed negligently, and designed defectively.

46. Defendant was under a duty to disclose to Plaintiff and her physicians, the

defective nature of the Defendant's Pelvic Mesh Products, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

47. Defendant had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Defendant's Pelvic Mesh Products.

48. Defendant's concealment and omissions of material fact concerning the safety of the Products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Products; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Defendant's Pelvic Mesh Products.

49. At the time these representations were made by Defendant, and at the time Plaintiff used the Products, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

50. Defendant knew and had reason to know that the Defendant's Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Defendant's Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

51. In reliance upon these false representations, Plaintiff was induced to, and did use the Products, thereby sustaining severe and permanent personal injuries and damages. Defendant knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding the use of the Defendant's Pelvic Mesh Products, as described in detail herein.

52. Plaintiff reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the Defendant's Pelvic Mesh Products.

53. Having knowledge based upon Defendant's research and testing, or lack thereof, Defendant blatantly and intentionally distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff s healthcare providers and physicians, that the Defendant's Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

54. Defendant had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff healthcare providers, and the United States Food and Drug Administration ("FDA").

55. The information distributed to the public, the medical community, the FDA, and Plaintiff, by Defendant included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Defendant's Pelvic Mesh Products.

56. Defendant intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Defendants' Pelvic Mesh Products specifically that the Products did not have dangerous and/or serious adverse health safety concerns, and that the Defendant's Pelvic Mesh Products were as safe or safer than other means of treating stress urinary incontinence and/or prolapse.

57. Defendant intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

58. Defendant chose to over-promote the purported safety, efficacy and benefits of the Defendant's Pelvic Mesh Products instead.

59. Defendant's intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Products; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Defendant's Pelvic Mesh Products.

60. Defendant made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Defendant's Pelvic Mesh Products had innovative beneficial properties and did not present serious health risks.

61. These representations, and others made by Defendant, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

62. These representations, and others made by Defendant, were made with the intention of deceiving and defrauding Plaintiff, and Plaintiff s healthcare professionals and were made in order to induce Plaintiff, and her healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the Defendant's Pelvic Mesh Products and their healthcare professionals to dispense, recommend, or prescribe the Defendant's Pelvic Mesh Products.

63. Defendant recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Defendant's Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

64. Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiff, as well as her healthcare professionals, into a false sense of security, so that Plaintiff and her healthcare providers would rely on Defendant's representations, and Plaintiff would request and purchase the Defendant's Pelvic Mesh Products, and that her healthcare providers would dispense, prescribe, and recommend the Defendants' Pelvic Mesh Products.

65. Defendant utilized direct-to-consumer advertising to market, promote, and advertise the Defendants' Pelvic Mesh Products.

66.. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Defendant's Pelvic Mesh Products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendant, nor would Plaintiff with reasonable diligence have discovered the

true facts or Defendant's misrepresentations.

67. Had Plaintiff known the true facts about the dangers mild serious health and/or safety risks of the Defendant's Pelvic Mesh Products, Plaintiff would not have purchased, used, or relied on Defendant's Pelvic Mesh Products.

68. Defendant's wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

. 69. As a proximate result of the Defendant's conduct Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT V
FRAUDULENT CONCEALMENT

70. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

71. Throughout the relevant time period, Defendant knew that its Pelvic Mesh Products were defective and unreasonably unsafe for their intended purpose.

72. Defendant fraudulently concealed from and/or failed to disclose to or warn Plaintiff, and her physicians and the medical community that its Pelvic Mesh Products were defective, unsafe, un-fit for the purposes intended, and that they were not of merchantable quality.

73. Defendant was under a duty to Plaintiff to disclose and warn of the defective

nature of the Products because:

a) Defendant was in a superior position to know the true quality, safety and efficacy of the Defendant's Pelvic Mesh Products;

b) Defendant knowingly made false claims about the safety and quality of the Defendant's Pelvic Mesh Products in the documents and marketing materials Defendant provided to the FDA, physicians, and the general public; and

c) Defendant fraudulently and affirmatively concealed tile defective nature of the Defendants' Pelvic Mesh Products from Plaintiff.

74. The facts concealed and/or not disclosed by Defendant to Plaintiff were material facts that reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendant's Pelvic Mesh Products.

75. Defendant intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiff would request and purchase the Defendant's Pelvic Mesh Products, and that their healthcare providers would dispense, prescribe, and recommend the Defendant's Pelvic Mesh Products, and Plaintiff justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendant's Pelvic Mesh Product.

76. Defendant, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of the Defendant's Pelvic Mesh Products, and arc subject to the same liability to Plaintiff for her pecuniary losses, as though Defendant had stated the non-existence of such material information regarding the Defendant's Pelvic Mesh Products' lack of safety and effectiveness and dangers and defects, and as though Defendant had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from

discovering the truth. Defendant therefore has liability for fraudulent concealment under all applicable law, including, inter alia, Restatement (Second) of Torts § 550 (1977).

77. As a proximate result of the Defendant's conduct, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory danlages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VI
CONSTRUCTIVE FRAUD

78. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

79. Defendant was in a unique position of knowledge concerning the quality, safety and efficacy of the Defendant's Pelvic Mesh Products, which knowledge is not possessed by Plaintiff or her physicians, and Defendant thereby hold a position of superiority over Plaintiff.

80. Despite its unique knowledge regarding the defective nature of the Defendant's Pelvic Mesh Products, Defendant continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Defendant's Pelvic Mesh Products, as compared to other products and forms of treatment.

81. For example, scientists in the recent study published in Obstetrics & Gynecology, August, 2010, found that the complication rate was so high that the clinical

trial was halted early.

82 Defendant has concealed and suppressed material information, including limited clinical testing, that would reveal that the Defendant's Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendant has misrepresented the safety and efficacy of the Products.

83. Upon information and belief, Defendant's misrepresentations are designed to induce physicians and Plaintiff to prescribe, dispense, recommend and/or purchase the Defendant's Pelvic Mesh Products. Plaintiff and the medical community have relied upon Defendant's representations.

84. Defendant took unconscionable advantage of its dominant position of knowledge with regard to Plaintiff and engaged in constructive fraud in their relationship with Plaintiff. Plaintiff reasonably relied on Defendant's representations.

85. As a proximate result of the Defendant's conduct, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VII
NEGLIGENT MISREPRESENTATION

86. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

87. Defendant has a duty to accurately and truthfully represent to the medical and healthcare community, and Plaintiff, that the Products had been tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendant, in fact, were false.

88. Defendant failed to exercise ordinary care in the representations concerning the Products while it was involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendant negligently misrepresented the Products' high risk of unreasonable, dangerous, adverse side effects.

89. Defendant breached its duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, her physicians, and the medical and healthcare community.

90. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendant as set forth herein, Defendant knew, and had reason to know, that the Products had been insufficiently tested, or had not been tested at all, and t\lat it lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

91. As a proximate result of the Defendant's conduct, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VIII
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

92. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

93. Defendant carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Pelvic Mesh Products to Plaintiff, carelessly and negligently concealing the harmful effects of the Defendant's Pelvic Mesh Products from Plaintiff, and carelessly and negligently misrepresented the quality, safety and efficacy of the products.

94. Plaintiff was directly impacted by Defendant's carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Products sold and distributed by Defendant.

95. As a proximate result of the Defendant's conduct, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant, for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IX
BREACH OF EXPRESS WARRANTY

96. Plaintiff realleges and incorporates each and every allegation of this Complaint as if each were set forth fully and completely herein.

97. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold the Defendant's Pelvic Mesh Products.

98. At all relevant times, Defendant intended that the Defendant's Pelvic Mesh Products be used in the manner that Plaintiff in fact used them and Defendant expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other oral contraceptives, and that it was adequately tested and fit for its intended use.

99. At all relevant times, Defendant was aware that consumers, including Plaintiff, would use the Products; which is to say that Plaintiff was a foreseeable user of the Defendant's Pelvic Mesh Products.

100. Plaintiff and/or her implanting physicians were at all relevant times in privity with Defendant.

101. The Defendant's Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendant.

102. Defendant breached various express warranties with respect to the

Products including the following particulars:

a) Defendant represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendant's Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Products;

b) Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendant's Pelvic Mesh Products were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and,

c) Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendant's Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the products.

103. In reliance upon Defendant's express warranty, Plaintiff was implanted with the Defendant's Pelvic Mesh Products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

104. At the time of making such express warranties, Defendant knew or should have known that the Defendant's Pelvic Mesh Products do not conform to these express representations because the Defendant's Pelvic Mesh Products were not safe and had numerous serious side effects, many of which Defendant did not accurately warn about, thus making the Defendant's Pelvic Mesh Products unreasonably unsafe for their intended purpose.

105. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff relied upon the representations and warranties of Defendant in connection with the use recommendation, description, and/or dispensing of the Defendant's

Pelvic Mesh Products.

106. Defendant breached its express warranties to Plaintiff in that the Defendant's Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

107. Defendant's breaches constituted violations of common law and Pennsylvania statutory principles.

108. As a proximate result of the Defendant's conduct, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT X
BREACH OF IMPLIED WARRANTY

109. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

110. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold the Defendant's Pelvic Mesh Products.

111. At all relevant times, Defendant intended that the Defendant's Pelvic Mesh Products be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Defendant impliedly warranted each product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

112. Defendant was aware that consumers, including Plaintiff or Plaintiff s physicians, would implant the Defendant's Pelvic Mesh Products in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of the Defendant's Pelvic Mesh Products.

113. Plaintiff and/or her physicians were at all relevant times in privity with Defendant.

114. The Defendant's Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they manufactured and sold by Defendant.

115. Defendant breached various implied warranties with respect to the Defendants' Pelvic Mesh Products, including the following particulars:

a) Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendant's Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Product

b) Defendant represented that the Defendant's Pelvic Mesh Products were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Defendant's Pelvic Mesh Products were not as safe or safer than alternatives available on the market; and

c) Defendant represented that the Defendant's Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the drug.

116. In reliance upon Defendant's implied warranty, Plaintiff used the Products as prescribed and in the foreseeable manner nom lally intended, recommended, promoted, and

marketed by Defendant.

117. Defendant breached its implied warranty to Plaintiff in that the Defendant' s Pelvic Mesh Products were not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of Common Law principles as well as 13 Pa. Stat. Ann. §§ 2314 et seq.

118. As a proximate result of the Defendant's conduct, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XI
VIOLATION OF PENNSYLVANIA CONSUMER PROTECTION ACT

119. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

120. Plaintiff purchased and used the Defendant's Pelvic Mesh Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendant's actions in violation of the consumer protection Jaws.

121. Had Defendant not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendant's Pelvic Mesh Products, and would not have incurred related medical costs and injury.

122. Defendant engaged in wrongful conduct while at the same time obtaining, under

false pretenses, moneys from Plaintiff for the Products that would not have been paid had Defendant not engaged in unfair and deceptive conduct.

123. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b) Advertising goods or services with the intent not to sell them as advertised; and,

c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

124. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendant's conduct directed at patients, physicians and consumers was to create demand for and sell the Defendant's Pelvic Mesh Products. Each aspect of Defendant's conduct combined to artificially create sales of the Defendant's Pelvic Mesh Products.

125. Defendant has a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendant's Pelvic Mesh Products.

126. Had Defendant not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Products and would not have incurred related medical costs.

127. Defendant's deceptive, unconscionable, or fraudulent representations and

material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

128. Defendant's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

129. Defendant has engaged in unfair competition or unfair or deceptive acts of trade practices or have made false representations in violation in PA. Stat. Ann. Tit. 73, §§ 201-1 to 201.9.3.

130. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendant was the supplier, manufacturer, advertiser, and seller, who is subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

131. Defendant violated the statute that were enacted in this state to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendant's Pelvic Mesh Products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

132. The actions and omissions of Defendant alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair,

deceptive, fraudulent and unconscionable trade and business practices and false advertising.

133. Defendant had actual knowledge of the defective and dangerous condition of the Defendant's Pelvic Mesh Products and failed to trade any action to cure such defective and dangerous conditions.

134. Plaintiff and the medical community relied upon Defendant's misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

135. Defendant's deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

136. By reason of the unlawful acts engaged in by Defendant, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

137. As a direct and proximate result of Defendant's violations of the states' consumer protection laws, Plaintiff has been injured catastrophically, and sustained severe and pei lnanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XII
GROSS NEGLIGENCE

138. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

139. The wrongs done by Defendant were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendant's conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendant's standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendant was actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendant, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

140. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

141. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

142. Plaintiff also alleges that the acts and omissions of named Defendant, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendant for its conduct and which would deter other manufacturers from engaging in such misconduct in the future.

143. As a direct and proximate result of Defendant's conduct, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT XIII
UNJUST ENRICHMENT

144. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

145. Defendant is and at all times was the manufacturer, seller, and/or supplier of the Defendant's Pelvic Mesh Products.

146. Plaintiff paid for the Defendant's Pelvic Mesh Products for the purpose of treatment of stress urinary incontinence.

147. Defendant has accepted payment by Plaintiff for the purchase of the Defendants' Pelvic Mesh Products.

148. Plaintiff has not received the safe and effective medical device for which they paid.

149. It would be inequitable for Defendant to keep this money if Plaintiff did not in fact receive a safe and effective medical device.

150. As a direct and proximate result of Defendant's conduct, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages and for costs in excess of $75,000.00 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

KLINE & SPECTER, PC.

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